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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,107	12/22/2005	Wai Ming Wong	P001.004.NPEUS	6273

56374 7590 03/04/2008
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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

MAIL DATE	DELIVERY MODE
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03/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,107	Applicant(s) WONG ET AL.
	Examiner Jeffrey E. Russel	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,8,14,16,17 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,8,14,16,17 and 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20070213</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. As requested by Applicants, the substitute specification filed July 12, 2007 will not be entered. The preliminary amendments filed December 22, 2005 and January 30, 2008 have been entered.

2. The abstract of the disclosure is objected to because it is insufficiently detailed with respect to the particular pharmaceutical uses of the tripeptide. Further, at line 3 of the Abstract, “said” is legal phraseology, and should be changed to “the”. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: Page 28, line 30, of the specification refers to “a nucleic sequence that encodes peptides of sequence ID No.1 to ID NO.30”. However, the specification does not recite any sequences identified by sequence ID No., and it is not clear to what sequences or peptides these sequence ID Nos. are referring.

Appropriate correction is required.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 16, 17, and 31-33 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original disclosure supporting the current method claims in which T-lymphocyte transformation is reduced, countered, or inhibited, or in which the tripeptide is present in an anti-T-cell transformation amount. The original disclosure is limited to

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the stimulation of T-lymphocyte transformation. See, e.g., the sentence bridging pages 1 and 2 of the specification, and originally-filed claim 15. Applicants have not indicated where the original disclosure of the invention supports the new claim limitation.

5. Claim 30 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 3 is limited to an “isolated, purified” peptide, and is limited to a peptide “consisting essentially of” a tripeptide. Dependent claim 30, however, recites a peptide which “comprises” a “substantially pure” tripeptide. The limitations “comprises” and “substantially pure” in dependent claim 30 are broader in scope than the limitations “consisting essentially of” and “isolated, purified” in independent claim 3, and accordingly dependent claim 30 is an improper dependent claim.

6. Claim 32 is objected to because of the following informalities: At claim 32, line 3, “cancer” is misspelled. Appropriate correction is required.

7. Instant claims 3, 8, and 30 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/483,272 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed subject matter.

Instant claims 14, 16, 17, and 31-33 are not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/483,272 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose a method in which T-lymphocyte transformation is reduced, countered, or inhibited, or in which the tripeptide is

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present in an anti-T-cell transformation amount, and does not disclose the treatment of lung cancer or melanoma.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 3 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by the Furka et al article (J. Comb. Chem., Vol. 2, pages 220-223). The Furka et al article teaches a combinatorial peptide synthesis in which the tripeptide YSV is synthesized attached to a Chiron crown. See, e.g., page 220, column 2, first full paragraph, and Table 3, position 20, String 4. The peptides attached to each crown are homogenous, i.e. meet Applicants' claim requirements of "isolated, purified".

10. Claims 3 and 30 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by the WO Patent Application 03/006492. The WO Patent Application '492 teaches the tripeptides YSF and YSL in isolated and purified form and which are used, e.g., to treat cancer. See, e.g., page 2, Table A, and claims 1 and 2. The tripeptides of the WO Patent Application '492 meet Applicants' requirement for a "peptide consisting essentially of a tripeptide of amino acid sequence L-Tyrosyl-L-Seryl-L-Valine". In the paragraph bridging pages 12 and 13 of Applicants' specification, Applicants define "consisting essentially of" as including functional

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derivatives of the tripeptide YSV. In the paragraph bridging pages 10 and 11 of the specification, Applicants define “functional derivatives” as including derivatives of the peptide, which are defined in the same paragraph as permitting conservative replacement of amino acids within the peptide. The tripeptides of the WO Patent Application ‘492, YSF and YSL, differ from YSV by a conservative (hydrophobic) amino acid replacement at position 3. Accordingly, the tripeptides of the WO Patent Application ‘492 consist essentially of the amino acid sequence YSV and therefore anticipate Applicants’ claims.

11. Claims 3 and 30 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by the WO Patent Application 02/087507. The WO Patent Application ‘507 teaches the tetrapeptide YSVT. See, e.g., claim 17, identified as SEQ ID NO:44, and page 13 of the attached sequence listing, identified as SEQ ID NO:43. In the paragraph bridging pages 12 and 13 of Applicants’ specification, Applicants define “consisting essentially of” as including functional derivatives of the tripeptide YSV. In the paragraph bridging pages 10 and 11 of the specification, Applicants define “functional derivatives” as including variants of the peptide, which are defined in the same paragraph as permitting additional amino acids to the termini of the peptide. The tetrapeptide of the WO Patent Application ‘507, YSVT, differs from YSV by one additional amino acid at the carboxyl termini of the tripeptide YSV. Accordingly, the tetrapeptide of the WO Patent Application ‘507 consists essentially of the amino acid sequence YSV and therefore anticipates Applicants’ claims.

12. Claims 3, 8, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Pang et al (U.S. Patent No. 5,739,274). Pang et al teach the tripeptide FMOC-Tyr-Ser-Val-OH in purified form, at column 21, lines 30-33. Note that the claims do not contain any language which

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excludes the possibility of an FMOC group at the N-terminus or the tripeptide. With respect to instant claim 8, because Pang et al teach the only component required by Applicants' pharmaceutical composition claim, Pang et al are deemed to anticipate this claim. Note also that an intended use limitation, i.e. "pharmaceutical", does not impart patentability to product claims where the product is otherwise anticipated by the prior art.

13. The WO Patent Application 03/006492 and the WO Patent Application 02/087507 are not deemed to anticipate or render obvious instant claims 8, 14, 16, 17, and 31-33. Note that these claims recite tripeptides, not a "peptide consisting essentially of a tripeptide". Especially in the absence of the "consisting essentially of" language, these claims do not embrace the tripeptides of the WO Patent Application '492 or the tetrapeptide of the WO Patent Application '507.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/

Primary Examiner, Art Unit 1654

JRussel

March 4, 2008